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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,396	01/23/2004	Terry Keith Bryant	1023.8009	8942
44538	7590	07/13/2007		
DANIEL S. POLLEY, P.A. 1215 EAST BROWARD BOULEVARD FORT LAUDERDALE, FL 33301			EXAMINER ASTORINO, MICHAEL C	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 07/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

ED

**Office Action Summary**

Application No.

10/767,396

Applicant(s)

BRYANT, TERRY KEITH

Examiner

Michael C. Astorino

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on April 18, 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-28, 30 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-28, 30 and 32-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The Examiner acknowledges Applicant's response filed April 18, 2007.

#### ***Specification***

The disclosure is objected to because of the following informalities: page 1, line 7, it is unclear to the examiner what the applicant is referring to by "disclosure document #504899."

Appropriate correction is required.

#### ***Claim Objections***

Claims 17 and 19 are objected to because of the following informalities: Claim 17, lines 4-5, the stricken through word "requires" should not be stricken through. Claim 19, line 8, "Signal Output" should not be capitalized. If there is a reason for the capitalization, Applicant is invited to inform the Examiner of the reason. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-28, 30 and 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to claim 3, "[a] medical apparatus used for a particular medical or therapeutic function, *as needed, of a type that conventionally requires* live human ancillary medical assistance to prompt, encourage, give measurements *or* guide a user in

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connection with utilization of said medical apparatus *or* in correlation with any medical procedure working in synthesis with said medical apparatus.”

First, it is unclear what “*as needed*” refers to. Otherwise stated, what are the metes and bounds of the phrase? Second, “*a type that conventionally requires*” refers to. Otherwise stated, what are the metes and bounds of the phrase? Lastly, the conjunction “or” has been used three times in the limitation above. The use of the conjunction makes it indefinite to determine the metes and bounds of the claimed limitation. Additionally, the phrase “*as needed*” in lines 4, 12 and 31, and “*for such purposes*” in lines 14 and 32 are indefinite.

Claim 10, line 7 the phrase “*as needed*” is indefinite.

Claim 13, line 5 the phrase “*as needed*” is indefinite.

Claim 17, line 5, the phrase “*a type that conventionally requires*” is indefinite.

Claim 19, line 17, the phrase “*as needed*” is indefinite.

Claim 20, line 5, the phrase “*as needed*” is indefinite.

Claim 21, line 9, the phrase “*as needed*” is indefinite.

Claim 22, lines 2-3, the phrase “*a type that conventionally requires*” is indefinite.

Claim 22, line 7, the phrase “*as needed*” is indefinite.

Claim 22, line 15, the phrase “*as needed*” is indefinite.

Claim 23, line 6, the phrase “*as needed*” is indefinite.

Claim 26, lines 4-5, the phrase “*as needed*” is indefinite.

Claim 28, lines 4, the phrase “*as needed*” is indefinite.

In regards to claims 17-21 and 34-35, only those claims using “means for” or “step for” modified by some functional language, as long as it is not modified by sufficient structure, material, or acts for achieving the specified function, will invoke 112.6<sup>th</sup> paragraph. In this application claim 17, a self-contained means is disclosed as being within a housing. In this application claim 18, means for verbally indicating and verbally responding is disclosed as being within a housing. Claims 34 and 35 further support Examiner’s position by adding more limitations on the structure. The means being within a housing modifies the means with sufficient structure and thus does not invoke 112.6<sup>th</sup> paragraph.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5, 9-11, 14-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al, U.S. Patent No. 6,126,613 A (Edwards).

Edwards teaches a method for using an incentive spirometer for improving lung performance by providing audibly and verbally instructions prompting the user of the spirometer and guiding the user through steps in operating the medical apparatus (see col. 2, lines 26-29 and col. 11, lines 13-17).

In regards to the structure of the apparatus Edwards teaches an incentive spirometer for improving lung performance by providing audibly and verbally instructions prompting the user

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of the spirometer and guiding the user through steps in operating the medical apparatus (see col. 2, lines 26-29 and col. 11, lines 13-17), comprising: sensors 131 and 153 (rotation detector and air composition detector) producing output signals and measuring human or therapeutic performance (see col. 6, lines 43-47, and col. 7, lines 18-22); a module 132 for a central processing unit (computerized device) (see col. 7, line 20); a module (voice system containing prerecorded instructions) for storing of program instructions, audio signals, and generating audible sound (see col. 11, lines 13-15); a module 302 (power source or battery) for conserving electrical power (see col. 11, lines 19-21); a module (counter or clock) determining accurate intervals of time (see col. 10, line 65 to col. 11, line 6); a module 135 (wireless transmitter) communicating remotely with a separate agent (see col. 11, line 23); and program instructions (software) controlling the actions or functions of the central processing unit or processor relating to the function of the spirometer and the "voice system" for operating the spirometer (see col. 11, line 17-19).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-28, 30, and 32-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Wessel US Patent Number 6,699,188.

Wessel teaches a system and method wherein patient is rewarded for performing a medical test or for maintaining medical test results within desired levels. Medical test data is generated and transferred for use by reward firmware in a cartridge, for example. Reward information is provided to the patient to motivate or encourage the patient to conduct medical tests and/or to maintain medical test results within certain levels. The cartridge can be inserted into an electronic controller, e.g. a handheld video-game controller, cellular telephone, or other device. Transmission of data and/or encouragement to and from a remote location provides additional advantages. More specifically, Wessel teaches:

Detailed Description Text (3):

Embodiments of the invention now will be described with more specific reference to the figures. According to one aspect of the invention illustrated in FIG. 1, handheld video game system 10 for use by a patient includes video-game controller 20 for receiving game cartridges. Video-game controller 20 includes first display 30 for entertaining or otherwise informing the patient, for example by displaying video-game graphics, charts, tables, or other information. Controller 20 also includes control buttons, keys, or similar manually activated devices 35, speaker 40, and other interactive features found e.g. on a conventional GAME BOY handheld gaming controller. Other types of controllers contemplated according to embodiments of the invention include PALM PILOT devices, personal digital assistants, cellular telephones, and/or other off-the-shelf computing devices.

Detailed Description Text (18):

Either medical circuitry 115, reward circuitry 125, or both, can include optional antennas 157, 158 or other wired/wireless transmission devices for remote communication. According to one example, new or modified reward or entertainment information can be communicated to cartridge 50 using e.g. BLUETOOTH wireless technology from e.g. a NINTENDO GAMECUBE or other device or location. Connection to a cellular or other wireless communication network is contemplated as well. SMS (short messaging service) or other text messages, graphical messages, and/or voice or other audio messages, can be communicated directly to cartridge 50 via one or more antennas 157, 158 for communication to the user via e.g. display 60. Such communication can provide direct encouragement or motivation, from or as initiated by a doctor, school nurse or other nurse, parent, or other interested person or entity, to encourage or motivate the user to maintain blood glucose values or other medical parameters within certain levels, and/or to maintain a certain testing frequency or regimen, for example.

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Such communication also can occur via e.g. display 30 of controller 20 or other portion of controller 20. Additionally, encouragement or other messages can be communicated via e.g. display 60 of cartridge 50 without the use of antennas 157, 158 or other external message-directive input; such messages can be pre-programmed within e.g. memory 105 of cartridge 50. Antennas 157 or 158, for example, also can be used to communicate a reply message from the patient via cartridge 50 (and/or controller 20) to the doctor, nurse or other person/entity. Alarm variables or settings, as described herein, also can be communicated via antennas 157 and/or 158.

Detailed Description Text (20):

FIGS. 4-5 show the front side and back side, respectively, of one suitable hardware representation of motivation circuitry 125. Microcontroller 130 is operatively coupled to medical circuitry 115 via data communication link(s) 145, and to controller 20 or other external device via line 155, as shown. Embodiments of the invention include features that allow controller 20 or other external device 20, or a remotely located medical professional or other person or entity, to input alarm variables that will be used to alert the patient, and/or to include alarm enunciation via audio and/or visual outputs of controller 20 as to an appropriate time to perform a medical test, when a medical test is overdue, etc. Actual testing time and preset alarm times can be stored by e.g. memory 105 or other memory/storage device. According to embodiments of the invention, audio, visual and/or textual features of cartridge 50 and/or controller 20 can be used to communicate alarm conditions, for example pre-programmed or downloaded alarm conditions, to the patient. For example, in the case where a child or other patient or user has inserted cartridge 50 into a GAME BOY controller or other controller 20 and has passed a deadline or other time for conducting a blood glucose test, then either display 30 of controller 20, or display 60 of cartridge 50, or both, can be activated to flash red as a reminder that a test should be conducted. An audio indication also or alternatively can be provided. Points, ammunition, game levels or other aspects of a pre-existing software game associated with controller 20 can be taken away or denied access, until the test is conducted or other condition that initiated the alarm, e.g. an unacceptable blood glucose level, is satisfied or resolved. As another example, according to cellular telephone embodiments described later in this application, a cellular service or other entity or person can send an SMS or other text message to the cellular phone, and/or generate a special ring or other audio or visual indication, alerting the user that an alarm condition exists and should be remedied or resolved.

Detailed Description Text (49):

The FIG. 26 embodiment is substantially similar to the FIG. 25 embodiment, except that a message look-up table is accessed at step 595 and a message is selected based on glucose test data or other medical data. An automated encouragement message is selected, at step 600. The message can include video, graphics, text, and/or audio to name several examples. At step 605, the patient's telephone 205 is dialed. At step 610, as one example, a "nice job" message or other encouragement message is displayed on e.g. display 30 of telephone 205. Previously referenced



memory locations are cleared at step 585, and the next download awaited.

### ***Response to Arguments***

Applicant's arguments filed April 18, 2007 have been fully considered but they are not persuasive.

#### **I. Edwards**

Applicant argues that Edwards cannot be used as prior art since it requires the use of the medical ancillary medical assistance to calibrate the device. However it is the Examiner's position that this view is unduly narrow and is not in concert with the broadest reasonable interpretation of the claims. It is the examiner's position that Edwards properly rejects the claims.

First, concerning the interpretation of the claims, Applicant uses language indicative of intended use for the "medical apparatus" and "self-contained electronic assembly." The word "for" does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use.

Second, concerning the claim limitation "... automatically verbally prompting or guiding a blind or sighted user ..." this phrasing does not require the prior art to verbally prompting a blind user. That is mere a sufficient condition not a necessary one to reject the claims. Otherwise stated, since the claimed limitation is drafted in the alternative via the conjunction "or" it is not required that Edwards teach verbally prompting a blind user ... Edwards sufficiently rejects the claims by guiding a sighted user. However, even if not claimed in the alternative, the recitation is intended use and does not change the structure of the device. As such it does not overcome the prior art.

Regarding Applicant's point about the AMA standards, AMA standards do not affect patentability.

## **II. Wessel**

Applicant argues that Wessel cannot be used as prior art since it is limited to a sighted user. As previously described above, the alleged limitation the device usable by persons who are blind does not affect the structure of the device as presently claimed. The limitations are added in the alternative and are intended use. Additionally, the term blind includes those who are legally blind. Those who are legally blind would be able to use the prior art inventions, Edwards and Wessel. Regarding the audio capabilities of Wessel, it is the Examiner's position that there is sufficient disclosure to reject the claims.

Regarding Applicant's point about the AMA standards and the use of the device for all patients, AMA standards and all possible patients do not affect patentability.

Regarding Wessel as not being a conventional medical apparatus, the term conventional or *a type that conventionally requires* is indefinite. As such, arguments based on this language are ineffective.

Regarding the Applicant's argument that Wessel is not a gauge. A gauge is measurement device. Wessel device is a measurement device.

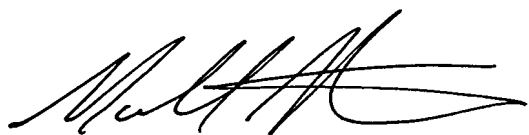
**The Applicant is invited to request an interview to discuss suggestions to overcome the applied prior art.**

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Michael C Astorino** whose telephone number is **571-272-4723**. The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Michael Astorino', with a stylized, flowing script.

Michael Astorino  
July 9, 2007